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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,114	06/22/2001	Seung-Ho Choi	19916-003001	9054

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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10/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/888,114	CHOI ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5-22 and 42 is/are pending in the application.
- 4a) Of the above claim(s) 6-11, and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,5,12,14-22 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/17/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 2, 3, 5-22, and 42 are pending in the application.
2. In the prior action, the Final action mailed on May 16, 2007, claims 2, 3, 5-22, and 42 were pending; with claims 2, 3, 5, 12, 14-22, and 42 under consideration and rejected; and claims 6-11, and 13 withdrawn as to non-elected inventions.
3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 17, 2007 has been entered.

In the Response filed with the RCE, the Applicant amended claims 2 and 42.

4. Claims 2, 3, 5, 12, 14-22, and 42 are currently under consideration.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on September 17, 2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Objections

6. **(Prior Objection- Withdrawn)** Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim

3 purports to further limit the inventions of claim 2 to embodiments comprising combinations of identified polymers. However, claim 2 read on a composition "consisting" of "a biopolymer." In view of the amendment of claim 2, the objection is withdrawn.

7. **(Prior Objection- Withdrawn)** Claim 42 is objected to because of the following informalities: the claim depends from a rejected claim. In view of the amendment of the claim, the objection is withdrawn.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **(New Rejection)** Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim reads on the composition of claim 2, wherein "the biopolymer" is selected from a provided group. However, it is noted that claim 2 refers to a composition having "at least one biopolymer." It is not clear from the claim language if the language "the biopolymer" of claim 3 is intended to refer to the one biopolymer required by claim 2, or is intended to indicate that each of the "at least one" biopolymers of claim 2 are selected from the indicated group.

Clarification of the claim language is required. Because the Office gives claims the broadest reasonable interpretation, claim 3 is read as defining the polymer of only the one required biopolymer.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **(Prior Rejection- Maintained)** Claims 2, 3, 5, 12, 14-22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Scott (6,458,387) in view of Watts (WO 98/30207), and further in light of the teachings of Noble (U.S. 4,574,152), Voser (U.S. 3,725,400), and Chromecek (U.S. 3,886,125). Applicant's arguments in traversal are noted. However, Applicant's arguments are based on the assumption that the present claims exclude the presence of a macromolecule such as is taught by Scott. It is noted that the Applicant has amended the claims to permit the presence of more than one biopolymer. See, claim 1 (now reading "at least one biopolymer"). It is noted that the term "biopolymer" has not been defined in the application to read on a particular form of polymeric material. Moreover, the term is understood in the art to refer to any "macromolecule which can be found within a living thing," including proteins, nucleic acids, and polysaccharides. See, the On-line Medical Dictionary (definition of "biopolymer"). Thus, the term biopolymer appears to encompass the macromolecules referred to in Scott. In view of this, the Applicant's arguments regarding the inclusion of such macromolecules by Scott are not found persuasive, and the rejection is maintained.

12. **(Prior Rejection- Maintained)** Claims 2, 3, 5, 12, 14-22, and 42 were rejected under 35 U.S.C. 103(a) as being unpatentable over Scott in view of Watts, Noble, Voser, and Chromecek

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as applied to claims 2, 3, 5, 12, 14-22 above, and further in view of Horwitz et al. (U.S. 5,783,561). The Applicant traverses this rejection on the same basis as asserted above. The rejection is therefore maintained for the reasons indicated above.

13. **(New Rejection)** Claims 2, 3, 5, 12, 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (WO 96/20698) in view of the teachings of Scott (6,458,387), and of Noble (U.S. 4,574,152), Voser (U.S. 3,725,400), and Chromecek (U.S. 3,886,125). As has been previously described, these claims are directed to compositions comprising at least one biopolymer, a cephalosporin entrained or bound to the polymer, a metal cation, and an adsorption enhancer.

Levy teaches microparticles made of polymers that entraining, or having surface bound, active agents. Pages 6-7, and 15 (lines 17-19). It is noted that the reference teaches that the polymers used may include several of the polymers suggested by claim 3 of the present application. Page 7. The Levy reference also indicates that permeation enhancers may be included in the described microparticles. Page 25, lines 4-6. It is noted that the art indicates that “permeation enhancers” is another term for the “absorption enhancers” required by the present claims. See e.g., U.S. 5,182,258 (column 8, lines 28-36); and U.S. 2007/0054964 (page 3, paragraph [0024]). The reference also indicates that such particles are useful for the delivery of any bioactive agent (page 8), including antibiotics (see e.g., page 11, line 9). However, the reference does not teach or suggest the use of a cationic metal in the particle, or the specific inclusion of a cephalosporin.

However, as was previously described in the teachings of Scott, it was known in the art to include complexing agents such as cationic metals in microparticles. Moreover, the teachings of the other cited references indicate that it was known in the art that cephalosporins form complexes with certain metal cations. It would therefore have been obvious to those of ordinary skill in the art to include such cationic metals in the particles of Levy to improve the incorporation of cephalosporins into the particles. The combined teachings of the references therefore render the claimed invention obvious.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

15. No claims are allowed.

16. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

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U.S. 6,902,743. This reference teaches polymeric compositions comprising cephalosporins. However, the reference does not teach or suggest the inclusion of cationic metals or absorption enhancers.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. Lucas/
Patent Examiner, AU 1648